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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,801	09/10/2003	Paolo Gatti	PC23575A	1817

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PFIZER INC
10555 SCIENCE CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER
SCHLIENTZ, NATHAN W

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~ipgslaj@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	10/658,801	GATTI, PAOLO	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *107,111,113 and 115-121* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *107,111,113 and 115-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/421,133, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed application fails to disclose the basic indolinone at 35-45% w/w, 10-16% w/w, or 15.2% w/w; the diluent at 10-86% w/w, 65-80% w/w, or 72.7% w/w; the binder at 2-20% w/w, 4-8% w/w, or 5.1% w/w; the disintegrant at 2-20% w/w or 5-10% w/w; and the lubricant at 1-10% w/w. The prior-filed application also fails to disclose that the formulation has a bulk density of at least about 0.50 kg/L or that more than 55% of the particles have a size of

less than 250 µm. Accordingly, claims 107, 111 and 113-120 are not entitled to the benefit of the prior application.

Status of Claims

Claims 107, 111, 113 and 115-121 are pending in this application and are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 107, 113, 115-117 and 120 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 107 and 120 recite 35-45% w/w sunitinib and 10-**86**% w/w of one or more pharmaceutically acceptable diluents. However, it is unclear how the composition can comprise up to 86% w/w

diluent if the composition must have a minimum of 35% w/w sunitinib (total would equal greater than 100%).

2. Claim 121 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 121 is dependent from itself thus rendering the claim unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 107, 113, 115-118, 120 and 121 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by O'Farrell et al. (WO 03/035009).

O'Farrell et al. disclose a composition according to Table 3 shown below, which is exactly the same as instant claim 118.

TABLE 3

COMPOSITION OF 5-(5-FLUORO-2-OXO-1,2-DIHYDRO-INDOL-3-YLIDENEMETHYL)-2,4-DIMETHYL-1H-PYRROLE-3-CARBOXYLIC ACID (2-DIETHYLAMINO-ETHYL)-AMIDE L-MALATE HARD GELATIN CAPSULES				
INGREDIENT NAME/GRADE	CONCENTRATION IN GRANULATION (% W/W)	AMOUNT IN 25 MG CAPSULE (MG)	AMOUNT IN 50 MG CAPSULE (MG)	AMOUNT IN 100 MG CAPSULE (MG)
API[A]	40.0	33.480[B]	66.800[C]	200.0[B]
MANNITOL	47.5	39.663	79.326	158.652
CROSCARAMELLOSE SODIUM[E]	6.0	5.010	10.029	20.04
POVIDONE (K-25)	5.0	4.175	8.350	16.700
MAGNESIUM STEARATE	1.5	1.252	2.504	5.008
CAPSULE	-	SIZE 3	SIZE 1	SIZE 0

2. Claims 107, 113, 115-118, 120 and 121 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by O'Farrell et al. (US 2003/0130280).

O'Farrell et al. disclose a composition according to Table 3 shown below, which is exactly the same as instant claim 118.

Composition of 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide L-malate hard gelatin capsules

Ingredient Name/Grade	Concentration in Granulation (% w/w)	Amount in 25 mg Capsule (mg)	Amount in 50 mg Capsule (mg)	Amount in 100 mg Capsule (mg)
API[a]	40.0	33.400[d]	66.800[c]	200.0[b]
Mannitol	47.5	39.663	79.326	158.652
Croscarmellose Sodium[e]	6.0	5.010	10.020	20.04
Povidone (K-25)	5.0	4.175	8.350	16.700
Magnesium Stearate	1.5	1.252	2.504	5.008
Capsule	—	Size 3	Size 1	Size 0

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 107, 111, 113 and 115-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shenoy et al. (WO 01/37820 A2) in view of Franz (US 4,609,675) and Oshlack et al. (US 6,077,533).

Determination of the scope and content of the prior art

(MPEP 2141.01)

With respect to Claim 111, Shenoy et al. teach a formulation comprising 0.01-***10*** wt.% ionizable substituted indolinone, 10-***80*** wt.% diluent, 0-***5*** wt.% binder, ***4***-10 wt.% disintegrant, and ***1***-1.5 wt.% lubricant (pages 92 and 93, Table: "All formulation components") (***emphasis added***).

With respect to Claims 107, 111, 113 and 115-119, Shenoy et al. teach a formulation comprising 15-75 wt.% ionizable substituted indolinone, 5-95 wt.% binder, 4-10 wt.% disintegrant, and 1-1.5 wt.% lubricant (page 96, 2nd Table, "Indolinone + Surfactant + Diluent + Binder + Disintegrant + Lubricant + Flow Enhancer").

Shenoy et al. further teach that 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide is a suitable ionizable substituted indolinone (page 39, compound 80; and pages 158-159, Example 80). Shenoy et al. also teach that the ionizable substituted indolinone contemplated for use are pharmaceutically acceptable salts which do not abrogate the biological activity and properties of the compound (page 60, lines 1-6), wherein the ionizable substituted indolinone is reacted with a molar equivalent of a base solution or an acid solution, such as malic acid (page 65, lines 1-4; page 76, lines 1-3).

Shenoy et al. also teach suitable pharmaceutically acceptable diluents include mannitol (page 73, lines 14-15); suitable pharmaceutically acceptable binders include polyvinylpyrrolidone (i.e. povidone) (page 73, lines 17-18); suitable pharmaceutically acceptable disintegrants include croscarmellose (page 73, lines 19-21); suitable pharmaceutically acceptable lubricants include magnesium stearate (page 73, lines 26-27).

With respect to Claim 113, Shenoy et al. teach that the broadest range of surfactants and flow enhancers encompasses 0 wt.% (pages 92 and 93, Table: "All formulation components"; and page 96, 2nd Table, "Indolinone + Surfactant + Diluent + Binder + Disintegrant + Lubricant + Flow Enhancer").

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Although Shenoy et al. teach 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide as a suitable ionizable substituted indolinone, and the acid solution comprising malic acid, Shenoy et al. do not explicitly teach the L-malate salt of 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide. However, it is well-known in the art at the time of the instant invention to employ pharmaceutically acceptable salts of compounds in pharmaceutical formulations in order to enhance the solubility of the compound, thus providing greater solubility. Shenoy et al. teach that salts tend to be more soluble in aqueous or other protonic solvents than are corresponding free base forms (page 87, lines 8-12).

Shenoy et al. do not teach the bulk density of their formulations to be at least 0.50 kg/L, at least 0.60 kg/L, or at least 0.64 kg/L, as instantly claimed. However, Franz teaches that drugs with high bulk density values reduce the volume or size of the tablet or capsule needed for a desired dosage per unit (col. 3, ln. 3-6 and 20-21). Franz teaches that high bulk density formulations are adaptable for further processing to make a range of solid dosage unit strength forms in smaller sized compressed tablets or filled capsule forms (col. 5, ln. 8-12). Franz further teaches that high bulk density (at least 0.4 g/ml, untapped, and at least 0.5 g/ml tapped) formulations can be incorporated into tablet and capsule end product pharmaceutical formulations with or without typical pharmaceutical adjuvants that result in dosage forms having reasonable tablet and capsule size limits that aid in patient acceptance (col. 8, ln. 39-50).

Also, Oshlack et al. teach powder-layered dosage forms wherein the therapeutically effective agents have a bulk density (poured and tapped) from about 0.2 g/ml to about 0.8 g/ml, more preferably from about 0.4 g/ml to about 0.75 g/ml (col. 7, ln. 60 - col. 8, ln. 1), wherein the layered beads are passed through a series of screens to remove undesirable sized beads, such as beads having diameters above 1.19 mm and below 0.84 mm (col. 8, ln. 59-63).

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to use the L-malate salt of 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-

amide in the formulations of Shenoy et al. because Shenoy et al. reasonably teach 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide as a suitable ionizable substituted indolinone and that salts tend to be more soluble in aqueous or other protonic solvents than are corresponding free base forms. It also would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to make the formulations of Shenoy et al. with a bulk density that is high enough to result in dosage forms having reasonable tablet and capsule size limits that aid in patient acceptance, as reasonably taught by Franz; as well as screening the particles for optimal size, such as between 0.84 and 1.19 mm, as reasonably taught by Oshlack et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's Remarks filed 06 July 2009 have been fully considered but they are not persuasive. Applicants argue on page 6 that one must make numerous selections in Shenoy et al. in order to arrive at the instant invention, such as selecting the active agent from over 260 compounds, selecting the L-malate salt from a list of possible salts, select the solid formulation even though Shenoy et al. teach that the suspension has

higher bioavailability, and selecting the specific component amounts in view of Shenoy et al. teaching extremely broad ranges.

The examiner respectfully argues that Shenoy et al. teach that in a particularly preferred embodiment the indolinone compounds include numerous compounds that are structurally similar to sunitinib and have an amine as opposed to carboxylic acid group (pg. 14). With respect to the selection of the malate salt of the ionizable substituted indolinones, Shenoy et al. clearly teach salts tend to be more soluble in aqueous or other protonic solvents than are the corresponding free base forms (pg. 87, ll. 11-12; and pg. 82, ll. 24-25). Shenoy et al. further teach that the ionizable substituted indolinones contemplated for use in their invention are pharmaceutically acceptable salts (pg. 60, ll. 1-2), and the indolinone is solubilized by combining it with a molar equivalent of a base or an acid solution (pg. 64), such as malic acid (pg. 65, ll. 1-4; pg. 76, ll. 1-3; pg. 79, l. 30 through pg. 80, l. 1; pg. 87, ll. 8-11; and claim 11). Therefore, Shenoy et al. clearly teaches the desire to use the pharmaceutically acceptable salt of the ionizable substituted indolinones, wherein malic acid is one of the preferred acid solutions for solubilizing said indolinones.

With respect to the concentration of the components, Shenoy et al. teach a set of ranges that is suitable for their invention, wherein the ionizable substituted indolinone is present from 5-90%, preferably 1-80%, and most preferably 15-75%, as acknowledged by Applicants (pg. 96, 2nd table). Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art to use the ionizable substituted indolinone at 35 to 45 wt.% as instantly claimed.

With respect to the presence of surfactant and/or flow enhancer, Shenoy et al. teach that the broadest range of surfactant and flow enhancer suitable for their invention includes 0%. Therefore, one of ordinary skill in the art would readily be able to determine whether surfactant and flow enhancer are necessary and in what amounts. Also, although it is not relied upon in the rejection, Tang et al. (US 6,573,293) show that one of ordinary skill in the art would be able to determine that surfactant and flow enhancer are not necessary with the teaching of a composition comprising indolinone (i.e., sunitinib L-malate), mannitol, croscarmellose sodium, PVP and magnesium stearate, wherein the compositions do not comprise any surfactant or flow enhancer (Table 2).

2. Claims 107, 111, 113 and 115-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al. (US 6,573,293) in view of Shenoy et al. (WO 01/37820 A2) and O'Farrell et al. (WO 03/035009 and US 2003/0130280).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Tang et al. teach compositions comprising pyrrole substituted 2-indolinone compounds and their pharmaceutically acceptable salts (Abstract). Tang et al. teach that the pharmaceutically acceptable salt is prepared by reacting the free base of the parent compound with inorganic acids, preferably hydrochloric acid or (L)-malic acid, such as the L-malate salt of 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl)-2,4-

dimethyl-1H-pyrrole-3-carboxylic acid (2-diethylamino-ethyl)-amide (col. 14, ln. 25-39). Tang et al. further teach compositions comprising:

TABLE 2

Ingredient Name/Grade	Concentration in Granulation (% w/w)	Amount in 50 mg Capsule (mg)	Amount in 200 mg Capsule (mg)
Formulation Code	J-011248-AA	J-011248-AA-00	J-011248-AA-01
Active Compound NF	65.0	50.0	200.0
Mannitol NF	23.5	18.1	72.4
Croscarmellose sodium NF	6.0	4.6	18.4
Povidone K 30 NF	5.0	3.8	15.2
Magnesium stearate NF	0.5	0.38	1.52
Capsule, Swedish yellow NF		Size 3	Size 0

Tang et al. teach that pharmaceutical compositions suitable for use in the present invention include compositions wherein the active ingredients are contained in an amount sufficient to achieve the intended purpose, e.g., the modulation of PK activity or the treatment or prevention of a PK-related disorder. Determination of a therapeutically effective amount is well within the capability of those skilled in the art (col. 174, ln. 3-47).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Tang et al. do not teach the indolinone compounds being present at 10-16% w/w, or 35-45% w/w, as instantly claimed. However, Tang et al. teach that one skilled in the art could readily determine the therapeutically effective amount. Also, Shenoy et al. teach indolinone containing compositions comprising 15-75% w/w indolinone (pg. 96,

2nd table). Also, O'Farrell et al. teach indolinone-containing compositions comprising 40% w/w sunitinib L-malate.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to determine the therapeutically effective amount of indolinone compound, such as sunitinib L-malate, for incorporation in the compositions according to Tang et al.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616